

**WHAT IS CLAIMED:**

1. In a blood dialysis system including a source of substitution fluid and a blood dialysis machine, a hemodiafiltration cartridge comprising:

a housing including a blood inlet which receives blood, a blood outlet which discharges diafiltered blood, a dialysate inlet for receiving a dialysate fluid and a dialysate outlet for discharging the dialysate fluid, the housing further including a plurality of semi-permeable filtering elements;

a member for dividing the housing into a first hemodiafiltration stage and a second hemodiafiltration stage, a first portion of the plurality of semi-permeable filtering elements being associated with the first stage and a second portion of the plurality of semi-permeable filtering elements being associated with the second stage, the blood inlet being in fluid communication only with the first stage, while the blood outlet is in fluid communication only with the second stage; and

an inter-stage section for providing fluid communication between the first and second stages, the inter-stage section including an inlet for receiving a substitution

fluid, wherein blood entering the blood inlet is partially diafiltered as it flows within the semi-permeable filtering elements of the first stage before being discharged into the inter-stage section where it is mixed with substitution fluid to form a blood/substitution mixture which then flows within the semi-permeable filtering elements of the second stage where further diafiltration occurs.

2. The system of claim 1, wherein the blood flows in a first direction in the first stage and in a second direction in the second stage.

3. The system of claim 2, wherein the dialysate fluid flows in the second direction relative to both the first and second stages.

4. The system of claim 1, wherein the housing includes a detachable first header cap disposed at a first end of the cartridge, the member including an inner wall formed as part of the first header cap, the inner wall dividing the first header cap into first and second inner header spaces.

5. The system of claim 4, wherein the first header cap includes the blood inlet which is in fluid communication with the first inner header space.

6. The system of claim 4, wherein the first inner header space is only in fluid communication with the filtering elements of the first stage, the second inner header space only being in fluid communication with the filtering elements of the second stage.

7. The system of claim 4, wherein the member includes a separator which divides the plurality of the filtering elements into the first and second stages.

8. The system of claim 7, wherein the separator comprises an annular ring disposed in a first potting compound at a first end of the plurality of filtering elements proximate to the blood inlet and blood outlet.

9. The system of claim 7, wherein the inner wall is aligned with the separator.

10. The system of claim 7, further including an O-ring disposed between the inner wall and the separator for sealing the first inner header space from the second inner header space.

11. The system of claim 7, wherein the separator includes a channel formed therein, the inner wall having a distal tip section which is attached to the separator within the channel.

12. The system of claim 1, further including a first potting compound surrounding the plurality of filtering elements at a first end thereof, and wherein the member comprises an inner wall of a first header cap that is connected to a first end of the housing, a distal tip section of the inner wall being disposed within the first potting compound so as to divide the plurality of filtering elements into the first and second stages.

13. The system of claim 4, wherein the blood outlet is formed in the first header cap so as to be in fluid communication only with the second inner header space.

14. The system of claim 1, further including a second header cap disposed at one end of the plurality of filtering elements so as to partial define the inter-stage connector, the second header cap having the substitution fluid inlet formed therein.

15. The system of claim 14, further including a second potting compound at the one end of the plurality of filtering elements, the second potting compound permitting each of the filtering elements to be in fluid communication with the inter-stage section.

16. The system of claim 1, further including a dialysate compartment defined by the housing and surrounding the filtering elements of the first and second stages, the dialysate inlet and outlet being in fluid communication with the dialysate compartment.

17. In a blood dialysis system including a source of substitution fluid, a blood dialysis machine, and a hemodiafiltration cartridge, the cartridge comprising:

a housing including a blood inlet which receives blood, a blood outlet which discharges diafiltered blood, a dialysate inlet for receiving a dialysate fluid and a dialysate outlet for discharging the dialysate fluid;

a member for dividing the housing into a first hemodiafiltration stage and a second hemodiafiltration stage, wherein the member permits the blood inlet to be in fluid communication only with the first stage while fluid communication is prevented between the blood inlet and the second stage, the blood outlet being in fluid communication only with the second stage;

a first filtering element associated with the first stage;

a second filtering element associated with the second stage; and

an inter-stage section for providing fluid communication between the first and second stages, the inter-stage section including an inlet for receiving the substitution fluid, wherein blood entering the blood inlet is partially diafiltered in the first stage before being discharged into the

inter-stage section where it is mixed with the substitution fluid to form a blood/substitution mixture which then flows within the second stage where further diafiltration occurs prior to the diafiltered blood being discharged through the blood outlet.

18. A dual-stage hemodiafiltration cartridge, the cartridge comprising:

a housing having a dialysate inlet and dialysate outlet;

a member dividing the housing into a first hemodiafiltration stage which receives blood through a blood inlet and a second hemodiafiltration stage, the member preventing the blood entering the blood inlet from fluidly communicating with the second stage;

an inter-stage section for providing fluid communication between the first and second stages, the inter-stage section including an inlet for receiving the substitution fluid, wherein blood entering the inter-stage section from the first stage has a first concentration of toxins, the blood being mixed in the inter-stage section with the substitution fluid to form a blood/substitution mixture which then flows within the second stage, the second stage having a blood outlet through which blood having a second concentration of toxins is

discharged, the first concentration of toxins being greater than the second concentration of toxins; and

wherein dialysate fluid flow is counter-current to blood flow in the first stage and co-current to blood flow in the second stage.

19. The dual stage cartridge of claim 18, wherein the housing includes first semi-permeable filtering elements associated with the first stage and second semi-permeable filtering elements associated with the second stage.

20. The dual-stage cartridge of claim 18, wherein the housing includes a first header cap disposed at a first end of the cartridge, the member including an inner wall formed as part of the first header cap, the inner wall dividing the first header cap into first and second inner header spaces, the blood inlet being in fluid communication only with the first inner header space, while the blood outlet is only in communication with the second inner header space.



21. The dual-stage cartridge of claim 20, wherein the first inner header space is only in fluid communication with the first semi-permeable filtering elements and the second inner header space is only in fluid communication with the second semi-permeable filtering elements.

22. The dual-stage cartridge of claim 20, wherein the member includes a separator which divides the plurality of the filtering elements into the first and second stages, the separator cooperating with the inner wall so as to define the first and second stages.

23. The dual-stage cartridge of claim 19, wherein the blood is diafiltered in each of the first and second stages by diffusion of toxins through the first and second semi-permeable filtering elements and by fluid conduction across the first and second semi-permeable filtering elements.

24. A dual-stage filtration cartridge comprising:

a housing having a first sterilization stage including first semi-permeable filtering elements and a second sterilization stage including second semi-permeable filtering elements, the housing having a first end and a second end with the first end including a fluid inlet port and a fluid outlet port and a member that divides the housing into the first sterilization stage and the second sterilization stage, first ends of the semi-permeable filtering elements being proximate to the first end of the housing, second ends of the semi-permeable filtering elements being proximate to the second end of the housing, the fluid inlet port being in fluid communication only with the first sterilization stage, while the fluid outlet port is in fluid communication only with the second sterilization stage, wherein the first and second semi-permeable filtering elements are sealed at the second end of the housing so as to cause the fluid entering the fluid inlet port to flow within lumen sections of the first semi-permeable filtering elements and then be filtered by being conducted across the first semi-permeable filtering elements and then subsequently being filtered again by being conducted across the second semi-permeable filtering elements and into the lumen sections of the second

semi-permeable filtering elements prior to being discharged through the fluid outlet port.

25. The dual-stage filtration cartridge of claim 24, wherein the first end of the housing includes a header cap defining an inner header space between the header cap and the first ends of the first and second semi-permeable filtering elements, the member including an inner partitioner formed as part of the header cap and dividing the inner header space into a first inner header space and a second inner header space, the fluid inlet port being in fluid communication only with the first inner header space while the fluid outlet port is in fluid communication only with the second inner header space.

26. The dual-stage filtration cartridge of claim 25, wherein each of the first and second inner header spaces has a semi-circular shape.

27. The dual-stage filtration cartridge of claim 25, wherein the inner partitioner comprises a pair of spaced inner walls extending cross-sectionally across the housing, one of the inner walls defining the first inner header space, the other of the inner walls defining the second inner header space.

28. The dual-stage filtration cartridge of claim 24, wherein the member includes a separating rib disposed at the first ends of the semi-permeable filtering elements so as to divide the semi-permeable filtering elements into the first and second semi-permeable elements.

29. The dual-stage filtration cartridge of claim 25, further including a first potting compound disposed at the first ends of the first and second semi-permeable filtering elements, the first potting compound permitting fluid communication between the first inner header space and the first semi-permeable filtering elements and the second inner header space and the second semi-permeable filtering elements.

30. The dual-stage filtration cartridge of claim 24, further including a second potting compound at the second ends of the first and second semi-permeable filtering elements for sealing off the second ends thereof.

31. The dual-stage filtration cartridge of claim 24, wherein the fluid enters the first stage and is discharged from the second stage both at the first end of the housing.

32. The dual-stage filtration cartridge of claim 24, wherein the first sterilization stage is independent from the second sterilization stage such that the second sterilization stage is a redundant sterilization stage with the fluid being completely filtered in each of the stages.

33. A method of hemodiafiltration comprising the steps of:

receiving a blood inflow;

diafiltering said blood inflow in a first stage to provide a partially diafiltered blood outflow;

mixing said partially diafiltered blood outflow with a substitution fluid to provide a blood/substitution fluid mixture; and

diafiltering said blood/substitution fluid mixture in a second stage, wherein both the first and second stages are included in a single cartridge housing.

34. A method of hemodiafiltration comprising the steps of:

receiving a blood inflow;

diafiltering said blood inflow in a first stage to provide a blood outflow having a first concentration of toxins;

mixing said partially diafiltered blood outflow with a substitution fluid at an inter-stage section to provide a blood/substitution fluid mixture; and

diafiltering said blood/substitution fluid mixture in a second stage to produce blood having a second concentration of toxins, the first concentration being greater than the second concentration, wherein dialysate fluid is common to both the first and second stages.

35. The method of claim 34, further including the steps of:

providing a dual-stage cartridge having a blood inlet at a first end for receiving the blood inflow and the inter-stage connector at a second end, wherein the dialysate fluid flows counter-current to the blood flowing in the first stage and co-current to the blood flowing the in the second stage.

36. A method for filtering a fluid, comprising:

- receiving a fluid at an inlet port of a dual-stage filtration cartridge;
- passing the fluid through a lumen section of a first filtering element;
- conducting the fluid across the first filtering element into an inner cavity of the housing;
- conducting the fluid across a second filtering element and into a lumen section thereof; and
- passing the fluid through the lumen section of the second filtering element to an outlet port through which the fluid is discharged, wherein the inlet and outlet ports are at the same end of the dual-stage cartridge and the first and second filtering elements each includes an open end and a closed end, the closed ends being at the same end of the dual-stage cartridge.

37. The method of claim 36, wherein at least a portion of the fluid flows in a first direction in the first filtering element and at least a portion of the fluid flows in a second direction in the second filtering element, the first and second directions being opposite one another.